REMARKS

Status of the Claims

Claims 1-12 and 19-29 are pending. Claims 22-29 have been withdrawn as directed to a non-elected invention. Claims 2-8 and 19 have been canceled without prejudice. Claims 30-33 have been added. Claims 1, 9-12, and 20-21 have been amended. Upon entry of this amendment, claims 1, 9-12, 20-21, and 30-35 will be pending.

Summary of the Amendment

Claim 1 has been amended to more clearly recite a composition that is effective to inhibit a T-cell immune response and that comprises a nucleic acid vaccine encoding a targeted antigen and the targeted antigen that is encoded by said nucleic acid vaccine encoding a targeted antigen, wherein the ratio of the nucleic acid vaccine to the polypeptide is stated in claim 1 and in dependent claims 30-35. Support for these amendments can be found throughout the specification and the claims as-filed.

Claims 9-12 and 20-21 have been amended to keep the language consistent with claim 1 from which each ultimately depends.

No new matter has been added.

Brief Summary of the Invention

The pending claims are directed to compositions that comprise a nucleic acid vaccine and a polypeptide that are effective to ***inhibit***, rather than enhance or induce, a T-cell immune response.

Amendments to the Specification

As requested by the Office, Applicants have provided a substitute specification. Applicants have provided two versions, a clean copy and a second marked up copy showing any additions. Applicants note that at page 7, lines 22 and 23 and at page 16, lines 3 and 4, the original specification had underlined portions of a nucleic acid sequence. These underlined nucleotides are retained in the substitute specification and do not represent an amendment to that

sequence. The substitute specification contains the line numbering and the page numbering that the Office requested.

Applicants have also amended the specification so that trademarks are capitalized and are accompanied by the generic terminology.

The specification has also been amended to add sequence identifier numbers to comply with requirements of 37 C.F.R. § 1.821-1.825.

The substitute specification and sequence listing contain no new matter.

Drawings

The Office has stated that new corrected drawings in compliance with 37 C.F.R. § 1.121(d) are allegedly required because the drawings submitted when the present application entered the national phase were blank. Applicants submit herewith the drawings that were inadvertently omitted when the application entered the national phase in the United States from the previously filed PCT application. The submitted drawings found on the replacement sheets are identical to the drawing present in the PCT application, to which the present application properly claimed priority to and incorporated by reference. Applicants respectfully assert that the attached drawings are in compliance with 37 C.F.R. § 1.121(d) and that no new matter has been added.

Sequence Listing

The Office alleges that the present application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 because it contains sequences that are not identified. Applicants provide herewith a paper copy and an electronic copy of the sequence listing in accordance with the requirements of 37 C.F.R. § 1.821-1.825. The specification has also been amended to add the sequence identifiers where applicable. The content of the paper and the computer readable copy of the sequence listings are the same and includes no new matter.

Double Patenting

Claims 1-6, 10-12, and 20 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 10, and 11 of co-pending application No. 11/644,435. The Office alleges that although the claims are not identical they are not patentably distinct from each other because the claims of co-pending application number 11/644,435 are drawn to a composition comprising a eukaryotic cell expression vector containing nucleotide sequences encoding an allergenic protein and the protein or polypeptide that comprises an antigenic epitope of said protein. The Office alleges that the vector comprises an RSV, CMV, or SV40 promoter and the vector is in the proportion to the protein in a ratio of 1:15 to 5:1. Since no claims in either application have been allowed, Applicants respectfully assert that there is no basis to reject the pending claims under the nonstatutory grounds of obviousness-type double patenting.

In view of the foregoing, Applicants respectfully request that the rejection under obviousness-type double patenting be withdrawn.

Claim Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1-12 and 19-21 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully disagree.

The Office alleges that claims 1-6 are allegedly indefinite due to the phrase "a targeted nucleic acid vaccine" because it is allegedly unclear how the vaccine is targeted. Claims 1-6 have been amended rendering this rejection moot as the phrase "a targeted nucleic acid vaccine" is no longer used.

The Office alleges that claims 1 and 5-6 are vague and indefinite due the phrase "active polypeptide from a targeted antigen." Although the phrase "active polypeptide from a targeted antigen" is not vague or indefinite the claims have been amended and this phrase is no longer present in the in pending claims. Therefore, the rejection of claims 1 and 5-6 for allegedly being indefinite due to the phrase "active polypeptide from a targeted antigen" is rendered moot.

The Office alleges that claim 1 is rendered vague and indefinite by the phrase "targeted pathogen nucleic acid vaccine." The rejection of claim 1 based upon this phrase is rendered moot because the phrase is no longer present in the pending claims.

The Office alleges that claims 2, 5, and 7 are rendered vague and indefinite by the phrase "comprises a single package or mixture." Claims 2, 5, and 7 have been canceled without prejudice rendering the rejection moot.

The Office alleges that claims 3, 4, 6, and 8 are rendered indefinite because the proportions do not have units and for the inadvertent use of the word "and" instead of the word "to." Claims 3, 4, 6, and 8 have been canceled rendering this rejection moot.

The Office alleges that claim 10 is indefinite for the term "nucleic acid vaccine" because there is allegedly insufficient antecedent basis for the element of the claim. The Office alleges that it is not clear whether "said nucleic acid vaccine" refers to the "targeted nucleic acid vaccine" or the "targeted pathogen nucleic acid vaccine." Claims 1 and 10 have been amended rendering this rejection moot. Claim 1 has been amended to recite only one type of nucleic acid vaccine and, therefore, claim 10 is clear and definite.

The Office alleges that claim 12 is rendered vague and indefinite by the phrase "wherein said eukaryote cell expression vector is a plasmid, virus, bacteriophage" because a bacteriophage is a virus that infects bacteria and therefore it is allegedly not clear how a bacteriophage can be a eukaryote cell expression vector. The term "bacteriophage" has been removed from claim 12, rendering this rejection moot.

The Office alleges that claim 20 is vague and indefinite because it is allegedly not clear whether "said nucleic acid vaccine" refers to the "targeted nucleic acid vaccine" or the "targeted pathogen nucleic acid vaccine." In view of the amendments to claim 1 and 10, Applicants respectfully assert that the claims are clear and definite.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112 be withdrawn because the claims are clear and definite.

Claim Rejection Under 35 U.S.C. § 102

Claims 1-2, 5, 9-12, and 20-21 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wen *et al.* (U.S. Patent No. 6,221,664). The Office alleges that Wen reference anticipates the pending claims because it discloses a vaccine composition comprising hepatitis B surface antigen and a plasmid that encodes the same antigen and also includes an adjuvant. The Office also alleges that the Wen reference discloses that the plasmid comprises a CMV promoter and thereby anticipates the claimed subject matter. Applicants respectfully disagree.

The Wen reference fails to anticipate the pending claims because the Wen reference fails to disclose a composition effective to inhibit a T-cell immune response that comprises a nucleic acid vaccine encoding a targeted antigen and a polypeptide comprising the targeted antigen that is encoded by said nucleic acid vaccine encoding a targeted antigen. The Wen reference did not anticipate the claims because the Wen reference discloses a composition that enhances or induces an immune response rather than inhibits a T-cell immune response. Applicants have amended the claims to make this feature more clear and definite. Therefore, the Wen reference also fails to anticipate the composition wherein ratio of the nucleic acid vaccine to the polypeptide is selected from the group consisting of 5:1 (w/w), from 2:1 to 10:1(w/w), from 1:5 to 5:1(w/w), from 1:2 to 1:10(w/w) and is effective to inhibit a T-cell immune response.

For a reference to anticipate a claim the reference must explicitly or inherently teach each and every element of the claim as arranged. Here, the Wen reference fails to teach a composition effective to inhibit a T-cell immune response. In contrast to inhibiting a T-cell immune response the Wen compositions induces immune responses. The Wen reference states "[w]hen this complex vaccine was used to immunize mice, enhanced specific humoral and cellular immune responses were induced." (Wen, Column 3, lines, 27-30). Additionally, the Wen reference fails to disclose the proportions recited in claims 1 and claims 30-35. The Wen reference states, "The quantity of recombinant plasmid DNA added is 20-100 times of the quantity of the antigen used." (Wen, Column 3, lines, 26-27). The ratio stated within the Wen reference do not overlap with the ratios stated in the pending claims.

Accordingly, the Wen reference fails to anticipate the pending claims because the Wen reference fails to disclose each and every element of the claims. In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

Claims 1-2, 5, 7, 9-12 and 19-21 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pundi *et al.* (WO 02/078732). The Office alleges that the Pundi reference discloses the elements of the claims. Applicants respectfully disagree.

The Pundi reference fails to anticipate the pending claims because the Pundi reference fails to disclose a composition effective to inhibit a T-cell immune response that comprises a nucleic acid vaccine encoding a targeted antigen and the targeted antigen that is encoded by said nucleic acid vaccine encoding a targeted antigen. Moreover, the Pundi reference fails to disclose the ratios stated in the pending claims. For a reference to anticipate a claim the reference must explicitly or inherently teach each and every element of the claim as arranged. Here, the Pundi reference fails to teach a composition that is effective to inhibit a T-cell immune response. In contrast to inhibiting a T-cell immune response the Pundi reference discloses compositions that induces or enhances immune responses. Additionally, the Pundi reference fails to disclose the proportions recited in claims 1 and claims 30-35.

Accordingly, the Pundi reference fails to anticipate the pending claims because the Pundi reference fails to disclose each and every element of the claims. In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-6, 9-12 and 20-21 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Wen reference and claims 1-12 and 19-21 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Pundi reference. The Office alleges that the claims only differ from the references by failing to disclose the claimed proportions. The Office alleges that there is no evidence that the proportions are "critical" to the claim and that the Pundi

reference states that the quantity of inactivated virus can vary widely. Applicants respectfully disagree that the claims are obvious.

As discussed above, the pending claims are directed to a composition that is effective to ***inhibit*** a T-cell immune response. In contrast, the Pundi and Wen references disclose compositions that are allegedly effective to enhance or induce an immune response, which is the opposite of the presently claimed compositions. In contrast to making the pending claims obvious the Wen and Pundi references teach away from the pending claims. A reference teaches away when one of skill in the art after reading the reference "would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path" disclosed in the reference. *In re Gurley* 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 2004). Explaining further the court stated, "a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *Id.* The Wen and Pundi references teach away because one of skill in the art reading the Wen and Pundi references would not believe that the pending compositions would be likely to be effective to inhibit a T-cell immune response.

The Wen reference states that "[w]hen this complex vaccine was used to immunize mice, enhanced specific humoral and cellular immune responses were induced." (Wen, Column 3, lines, 27-30). One of skill in the art reading the Wen reference would not be led in the direction to use the composition to inhibit a T-cell immune response since the Wen reference teaches that such compositions enhance and induce cellular immune response. Therefore, the Wen reference teaches away from the pending claims.

The Pundi reference also teaches away from the pending claims. The Pundi reference states that the compositions disclosed induce a protected immune response. (Pundi, page 1, lines 9-11). The Pundi reference states that the potency of its compositions "refers to the ability of the vaccine to induce virus neutralizing antibodies and/or to protect the immunized host against subsequent virus challenge." (Pundi, p. 5, lines 6-8). Therefore, one of skill in the art would read the Pundi reference as teaching compositions that enhance or induce a T-cell immune response as opposed to a composition that is effective to inhibit a T-cell immune response. The

Pundi reference teaches away because it teaches the opposite of effect of what is presently claimed.

Additionally, the combination of the references does not yield the present invention because the ratios recited in the claims are not found in the references. The references also do not suggest or teach modifying the references to yield the present invention. Thus, even if the references were combined the references do not yield a T-cell immune response inhibitor comprising the elements recited in the claims in the ratios recited. Accordingly, the combination of the references fails to render the claims obvious because one of skill in the art would not have produced the present invention even if the references were combined.

Therefore, because the Pundi and Wen references teach away from the pending claims the claims and the combination of the references fails to yield the present invention the claims are not obvious. In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

Conclusion

Claims 1, 9-12, 18-21, and 30-35 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7820 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

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